

## **REMARKS**

### **I. Claim Status**

Reconsideration of the present application is respectfully requested. Claims 1-9, 11-13, 15, 17 and 31-34 are pending. Claims 10, 14, 16 and 18-30 are cancelled without prejudice. Claims 33 and 34 are new and are supported by the specification and claims as originally filed, for example, at page 11, paragraph 25. No new matter has been added to the claims by these amendments. Applicants thank the Examiner for withdrawing the rejections of the claims under 103(a).

### **II. Rejections Under 35 U.S.C. § 103(a)**

- A. U.S. Patent No. 5,985,918 to Modak et al. and U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Publication No. 2002/0098159 to Wei et al.

Claims 1-9, 11-13, 15, 17 and 31-32 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,985,918 to Modak et al. (hereafter “Modak”) and U.S. Patent No. 5,965,610 to Modak et al. (hereafter “the ‘610 patent”), in view of U.S. Publication No. 2002/0098159 to Wei et al. (hereafter “Wei”). The Examiner contends that Modak describes anti-irritant topical formulations comprising water, emollients and two or more organic salts of zinc in a concentration of between 0.1-15%. The Examiner further alleges that the ‘610 patent describes an anti-irritant gel comprising 1-10% zinc gluconate, 1-10% incoquat behenyl TMS, water, emollients and 0.4-4% of an antimicrobial agent such as chlorhexidine gluconate. The Examiner further states that Wei describes topical cream compositions comprising farnesol and antimicrobial agents such as benzalkonium chloride. According to the Examiner, the composition defined by the three references comprises all the elements of the pending claims, rendering the claims obvious.

Applicants respectfully disagree. The claims as amended are not obvious over the cited references when considered separately or in combination. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than

predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

Applicants submit that new claims 33 and 34 are not obvious over the cited references because the combined teaching of Modak, the ‘610 patent and Wei does not disclose all of the elements of the claimed invention. Claims 33 and 34 are directed to an anti-irritant composition comprising, among other ingredients, two or more water-soluble, organic salts of zinc, wherein the composition does not comprise zinc salicylate. In the instant office action, the Examiner relies on Modak for its disclosure of an anti-irritant topical formulation comprising two or more organic salts of zinc. Specifically, the Examiner states that:

Further, in addition to zinc salicylate, the composition may comprise one or more other organic salts of zinc, thus motivating the inclusion of “two or more” zinc salts as recited in instant claim 1 . . .

(*See* the January 22, 2009 office action (hereafter “the office action”), at page 4, emphasis added). Thus, any composition comprising two or more organic salts of zinc, in view of Modak, must include zinc salicylate as at least one of the species of organic zinc salts. *See* Modak, Col. 2, lines 27-67. In contrast, new claims 33 and 34 describe an anti-irritant composition that does not encompass zinc salicylate, and as such, the composition defined by the combined teaching of the cited references does not describe the claimed invention as recited by new claims 33 and 34, and does not render the new claims obvious.

Furthermore, as discussed in the previously filed response, the claims of the instant application are not obvious over the cited references because practicing the claimed invention produces surprising and unexpected results which a person of ordinary skill in the art would not have predicted in view of the cited references. *See* M.P.E.P. § 716.02(a) and § 2143.02; *see also In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

First, Applicants submit that the reduction in irritation achieved by using low concentrations of water-soluble organic zinc salts in an anti-irritant composition, as recited by the pending claims, would not have been predicted by an artisan of ordinary skill in view of Modak, the ‘610 patent and Wei. Dermal irritation can be caused by many different ingredients used in compositions designed for topical administration. For example, topical compositions may cause irritation due to ingredients such as spermicides, microbicides or alcohol-based gels. *See* the specification at page 4, paragraph 9. In the present application, Applicants have

discovered that irritation caused by compositions comprising these various ingredients could be reduced by incorporating low concentrations of zinc salts into the composition. For example, Examples 2 and 7 of the instant application (*see* pages 29-31 and 43-44) disclose that compositions comprising two or more zinc salts at low concentrations (*i.e.*, between 0.1 and 1%; and between 0.1 and 2%, respectively), were able to reduce irritation caused by a skin irritant (*i.e.*, methyl salicylate, *see* Example 2), or by latex-induced contact dermatitis (*see* Example 7). Furthermore, these reductions in irritation were achieved both in the presence (*see* Example 2) and absence (*see* Example 7) of an antimicrobial agent. Additionally, low concentrations of zinc salts (*i.e.*, 0.3% zinc gluconate, 0.1% zinc lactate and 0.1% zinc acetate) were able to reduce alcohol-induced irritation. *See* Example 8, page 45.

As contended by the Examiner, Modak and the '610 patent disclose that zinc salts may be incorporated into compositions at concentrations of between 1-15% or 1-10%, respectively, for reducing irritation. *See* the office action at page 4. Such zinc salts are allegedly useful for reducing irritation caused by a wide range of irritants, including latex, plant substances, pet allergens, cosmetics, perfumes, pollen, detergents, disinfectants, etc. *See* Modak at Col. 3, lines 5-10. However, Modak provides a person of ordinary skill with no guidance as to what concentrations of zinc salts would be effective in reducing irritation caused by such an expansive group of irritants. At best, Modak suggests that high zinc salt concentrations are necessary to reduce irritation. For example, as described in Modak's Examples, zinc salt concentrations above 2% were necessary for reducing latex induced irritation. *See* Modak, Col. 3, Table A. Specifically, a composition comprising 2% zinc acetate was unable to reduce latex induced irritation, and even a 5% zinc undecylenate composition did not prevent reactions to the latex. Thus, the skilled artisan, at best, would predict that zinc salts would need to be used at concentrations greater than 2% to reduce irritation.

Additionally, Applicants note that the claims as amended include ingredients such as an antimicrobial compound, farnesol, and ethanol, all of which can cause irritation when applied topically. *See, e.g.*, the specification at Example 5, pages 36-37; Example 8, page 45; and Example 13, pages 55-60. Modak does not suggest or describe any concentrations of water-soluble organic zinc salts that would be effective to reduce irritation caused by such ingredients. As such, Modak provides no basis to conclude that a skilled artisan would predict that low zinc salt concentrations, as encompassed by the present claims, would be effective to reduce irritation

induced by the specific ingredients recited by the claims. Indeed, Modak's own Examples, as previously discussed, disclose that zinc salts only reduced irritation when used at high concentrations greater than 2%. Therefore, in contrast to the composition encompassed by the claims of the instant application, a skilled artisan would predict that high concentrations of zinc salts would be necessary to reduce irritation.

Similar to Modak, the '610 patent merely discloses that zinc salts can prevent multiple irritant-inactivating substances from binding to a surface. *See, e.g.*, the '610 patent at Col. 4, line 57 - Col. 6, line 8. The patent provides no examples in which a water-soluble, organic salt of zinc reduced irritation caused by any irritant, let alone the agents encompassed by the amended claims. Thus, the '610 patent, like Modak, provides no basis for a skilled artisan to predicted that the low zinc salt concentrations of the presently claimed invention would have been capable of reducing irritation, and as such, the claims as amended are not obvious over the cited references.

Secondly, the claims as amended are directed to an anti-irritant composition comprising, among other ingredients, an antimicrobial compound, incroquat, farnesol and ethanol (*see, e.g.*, claim 1), all of which can cause irritation, as previously discussed. As disclosed in the Examples of the instant application, irritation induced by each of these ingredients can be reduced by combining two or more zinc salts at low concentrations with such ingredients in a single composition. *See, e.g.*, Example 2, pages 29-31; Example 8, page 45; and Example 13, pages 55-60. In contrast, Modak, the '610 patent and Wei disclose lists of various agents and ingredients that may be included in an antimicrobial composition. However, the references provide no basis for a skilled artisan to predict that such agents could be successfully combined into a single formulation with zinc salts, wherein the zinc salts reduced irritation induced by the agents.

In particular, Wei does not disclose that any of the agents identified in the reference are compatible with water-soluble organic zinc salts. Furthermore, the '610 patent discloses that in attempting to form a gel-matrix with an antimicrobial agent (*i.e.*, chlorhexidine gluconate), zinc gluconate was the only metal salt that could be formulated with the antimicrobial to successfully produce the gel-matrix, as "other zinc salts mixed with [chlorhexidine gluconate] did not form a gel matrix." *See* the '610 patent at Col. 7, lines 24-37. Thus, because different zinc salts can exhibit different properties with regard to combination formulations, as evidenced by the '610

patent, an artisan of ordinary skill would not have predicted that any zinc salt, let alone two or more zinc salts, could be successfully combined in a single composition with an antimicrobial agent, as recited in the amended claims. As the successful combination of zinc salts, an antimicrobial agent, and other ingredients recited by the claims would not have been predicted by a skilled artisan in view of the cited references, the claims can not be considered obvious in view of the prior art.

Third, the nonobviousness of the claims as amended is further evidenced by the surprising and unexpected synergistic antimicrobial effect achieved by combining the elements recited by the claims together in a single composition. As described in Example 10 of the application (*see* pages 47-52), the combination of chlorhexidine gluconate, benzalkonium chloride and incroquat in a single composition resulted in an antimicrobial effect that was greater than the expected additive effect of three compounds. Specifically, a composition comprising chlorhexidine gluconate and benzalkonium chloride exhibited a ten-fold reduction in recovered bacteria compared to a control composition, while a composition containing incroquat only exhibited a 0.48 fold reduction in bacteria compared to control. When the three agents were combined together in a single composition, a 4-log reduction in bacteria was achieved compared to the control composition. *See* the specification at page 48, paragraph 93; page 48, Table 10; and page 49, Table 11. Furthermore, adding low concentrations of zinc salts to the composition comprising the three agents did not reduce the antimicrobial effectiveness of the composition. *See* page 50, Table 12.

Thus, in view of the cited references' failure to describe all the elements of the claimed invention, in addition to the unexpected reduction of irritation and the synergistic antimicrobial effect achieved by the claimed invention, Applicants submit that the claims as amended are not obvious over the cited references, and respectfully request that the rejection be withdrawn.

B. U.S. Publication No. 2003/0152644 to Modak et al and U.S. Patent No. 5,985,918 to Modak et al. in view of U.S. Publication No. 2002/0098159 to Wei et al.

Claims 1-9, 11-13, 15, 17 and 31-32 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Publication No. 2003/0152644 to Modak et al. (hereafter "the '644 application") and Modak in view of Wei. The Examiner contends that Modak describes an anti-irritant composition comprising two organic zinc salts, as discussed above, and that the '644 application

discloses anti-irritant formulations comprising synergistic amounts of octoxyglycerin and an antimicrobial agent, in addition to zinc salts, incoquat behenyl TMS, emollients, thickening agents and gelling agents, among other ingredients. The Examiner further relies on Wei for its disclosure of farnesol, as previously discussed. According to the Examiner, the composition described by the combined disclosure of the three references discloses all the elements of the pending claims, rendering the claims obvious.

Applicants respectfully traverse the rejection. With regard to the '644 application, as noted by the Examiner, the '644 application is relied upon as prior art under 35 U.S.C. § 102(e), and the rejection under 35 U.S.C. § 103(a) may be overcome by showing that the reference is disqualified as prior art under 35 U.S.C. § 103(c). According to 35 U.S.C. § 103(c)

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

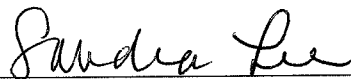
*See* 35 U.S.C. § 103(c); M.P.E.P. §§ 706.02(l)(1) and 706.02(1)(2). As described in the attached "Declaration Under 37 C.F.R. § 1.132" (Exhibit A), the claimed invention of the instant application and the '644 application were commonly owned, or subject to an obligation of assignment, to the same person, at the time the claimed invention was made. Specifically, on July 17, 2003, the filing date of the instant application, the '644 application was assigned to the Trustees of Columbia University in the City of New York (*See* the assignment recorded at reel 012966 frame 0993), while the claimed invention of the instant application was subject to an obligation of assignment to the Trustees of Columbia University in the City of New York. Thus, the '644 application is disqualified as prior art under 35 U.S.C. § 103(c), and Applicants respectfully request that the rejection be withdrawn.

**III. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fee is due at this time. However, if any fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,  
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